Health Committee 1

Amendment No. 1 to HB0317

Ramsey
Signature of Sponsor

AMEND Senate Bill No. 582 House Bill No. 317*

by deleting all language after the enacting clause and by substituting instead the following:

SECTION 1. Tennessee Code Annotated, Section 63-10-204(4), is amended by adding the following new language as new subdivisions:

(D) For use in a licensed prescribing practitioner's office for administration to the prescribing practitioner's patient or patients when the product is not commercially available upon receipt of an order from the prescriber;

(E) For use in a health care facility for administration to a patient or patients receiving treatment or services provided by that facility when the product is not commercially available upon receipt of an order from an authorized licensed medical practitioner of the facility;

(F) For use by emergency medical services for administration to a patient or patients receiving services from them under authorized medical control when the product is not commercially available upon receipt of an order from a licensed prescriber authorized to provide medical control; or

(G) For use by a licensed veterinarian for administration to their non-human patient or patients or for dispensing to non-human patients in the course of the practice of veterinary medicine upon receipt of an order from a veterinarian when the product is not commercially available.

SECTION 2. Tennessee Code Annotated, Section 63-10-204(12), is amended by inserting the following new language following the words "to a patient or the patient's agent" and before "by or pursuant to the lawful order of a prescriber":

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, to include a licensed healthcare practitioner or a health care facility providing services or treatment to the patient or patients,

SECTION 3. Tennessee Code Annotated, Title 63, Chapter 10, Part 2, is amended by adding the following as a new section:

63-10-216.

(a) Prior to initial licensure in this state as a compounding pharmacy, a pharmacy located outside of this state must have an inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located. Out-of-state pharmacy practice sites must provide a copy of the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located, which must have been within the previous twelve (12) months. Prior to renewal of its license in this state, an out-of-state pharmacy practice site must provide the most recent inspection by the regulatory or licensing agency of the state in which the pharmacy practice site is physically located or equivalent regulatory entity, and which must have been within the previous twelve (12) months. The board of pharmacy shall have the right to require additional information before issuing or renewing a pharmacy license to insure compliance with applicable laws of this state and any rules, and policies of the board.

(b) Any compounding pharmacy having an active Tennessee license shall notify the board within fourteen (14) business days of receipt of any order or

decision by a regulatory agency, other than the Tennessee board of pharmacy, imposing any disciplinary action, including any warning, on the pharmacy.

(c) Any pharmacies engaged in sterile compounding must comply with relevant United States Pharmacopeia (USP) guidelines as adopted by the board by rule or policy.

(d) Any pharmacies engaging in sterile compounding shall report, on a quarterly basis, to the board the quantity of sterile compounded products dispensed in a defined time period, in accordance with rules or policies adopted by the board.

SECTION 4. This act shall take effect upon becoming a law, the public welfare requiring it.